

K111919

DEC 22 2011

1 (3)

# Phadia

## 510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

### Premarket Notification 510(k) No:

**Date of Summary Preparation:** July 4, 2011

**Distributor:** Phadia US Inc.  
4169 Commercial Avenue  
Portage, MI 49002  
269-492-1957

**Manufacturer:** Phadia AB  
Rapsgatan 7P  
SE-754 50 Uppsala, Sweden

**Company Contact Person:** Martin Mann  
Regulatory Affairs Manager  
Phadia US Inc.  
4165 Commercial Avenue  
Portage, MI 49002  
269-492-1957

### Device Names:

ImmunoCAP Allergen f425, Allergen component rCor a 8, Hazel nut  
ImmunoCAP Allergen f428, Allergen component rCor a 1, PR-10, Hazel nut  
ImmunoCAP Allergen g205, Allergen component rPhl p 1, Timothy  
ImmunoCAP Allergen g206, Allergen component rPhl p 2, Timothy  
ImmunoCAP Allergen g209, Allergen component rPhl p 6, Timothy  
ImmunoCAP Allergen g210, Allergen component rPhl p 7, Timothy  
ImmunoCAP Allergen g212, Allergen component rPhl p 12, Profilin, Timothy  
ImmunoCAP Allergen g215, Allergen component rPhl p 5b, Timothy  
ImmunoCAP Allergen t215, Allergen component rBet v 1, PR-10, Birch  
ImmunoCAP Allergen t216, Allergen component rBet v 2, Profilin, Birch  
ImmunoCAP Allergen t220, Allergen component rBet v 4, Birch  
ImmunoCAP Allergen t225, Allergen component rBet v 6, Birch

### Common Name:

Automated in vitro quantitative assay for the measurement of allergen specific IgE antibodies.

**Classification:**

<u>Product Name</u>	ImmunoCAP Allergen Components
<u>Product Code</u>	DHB
<u>Class</u>	II
<u>CFR</u>	866.5750

**Substantial Equivalence to:**

ImmunoCAP Specific IgE	(k051218)
UniCAP 100	(k962274)

**Indications For Use Statement**

ImmunoCAP Specific IgE is an in vitro quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, and Phadia 1000. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

**Device Description****Reagents**

ImmunoCAP Specific IgE reagents are modular in concept and are available individually. For a complete listing of reagents needed to perform the Phadia ImmunoCAP Specific IgE assay, please consult the ImmunoCAP Specific IgE Conjugate Directions for Use.

**Instrument System**

Phadia 100, Phadia 250 and Phadia 1000 instruments with built-in software process all steps of the assay and print results automatically after the assay is completed.

**ImmunoCAP Specific IgE, Test Principle**

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient sample. After washing away non-specific IgE, enzyme labeled antibodies against IgE are added to form a complex. After incubation, unbound enzyme-anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The higher the response value, the more specific IgE is present in the specimen. To evaluate the test results, the responses for the patient samples are transformed to concentrations with the use of a calibration curve.

## **Performance characteristics**

The new ImmunoCAP Allergen Components were compared with the extract based predicate devices with the use of clinical samples, as well as samples from healthy, non-atopic donors. The performance characteristics of the new ImmunoCAP Allergen Components were established through studies of Precision including Lot-to-Lot Reproducibility, Linearity and Limit of Detection. Inhibition studies verified the immunological specificity of the allergen components.

## **Conclusion**

The safety and effectiveness of the cleared device ImmunoCAP Specific IgE system for the determination of specific IgE antibodies have been established in previous 510(k) submissions. This submission covers the addition of 12 new ImmunoCAP Allergen Components to the existing ImmunoCAP Specific IgE assay. No changes are made to the Intended Use or in the Indications for Use statements.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Phadia US Inc.  
c/o Mr. Martin Mann  
Regulatory Affairs Manager  
4169 Commercial Avenue  
Portage, MI 49002

DEC 22 2011

Re: k111919

Trade/Device Name: ImmunoCAP Allergen Components  
Regulation Number: 21 CFR §866.5750  
Regulation Name: Radioallergosorbent (RAST) immunological test system  
Regulatory Class: Class II  
Product Code: DHB  
Dated: December 21, 2011  
Received: December 22, 2011

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.  
Director  
Division of Immunology and Hematology Devices  
Office of *In Vitro* Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K111919

Device Name: ImmunoCAP Specific IgE

### Indications For Use:

ImmunoCAP Specific IgE is an *in vitro* quantitative assay for the measurement of allergen specific IgE in human serum or plasma (EDTA or Na-Heparin). ImmunoCAP Specific IgE is to be used with instruments Phadia 100, Phadia 250, and Phadia 1000. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

✓

Maria M. Chan  
Division Sign-Off

Page 1 of \_\_\_\_\_

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K111919